K130650

FEB 26 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: k130650

1. Date of Summary: January 10, 2014

2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   Phone: 732-274-1000
   Fax: 732-274-1010

3. Device Trade Names: Status DS™ OXY

4. Regulatory Information:
   4.1. Regulation section: 21 CFR 862.3650, Enzyme Immunoassay, Opiates
   4.2. Classification: Class II
   4.3. Product Code: DJG
   4.4. Panel: Toxicology (91)

5. Identification of legally marketed devices to which claims of equivalence are made:
   K060351: MedTox Oxycodone by MedTox Diagnostics

6. Device Description: The Status DSTM OXY test device is a simple immuno-chromatographic test for the rapid, qualitative detection of oxycodone and/or their metabolites in human urine. The test may be read visually or by using a DXpress™ Reader. The DXpress reader captures an image of an inserted compatible test device and uses a software algorithm to calculate the intensity of the test line. The DXpress reader interprets test result automatically by comparing the intensity of the test line to the preset cutoff value. In addition, the software will use the presence of the control line to determine whether or not the test result is valid.

7. Intended Use: The Status DS™ OXY is an immunochromatograhic test for the qualitative detection of Oxycodone in urine samples. The detection cut-off concentration of Oxycodone is 100 ng/mL. The test may be read visually or by using a DXpress™ Reader. It is intended for clinical laboratory use only.
   This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to the test result, particularly when preliminary positive results are obtained.

8. Substantial Equivalence: The Status DS™ OXY test was compared to the MedTox Oxycodone, k060351 by MedTox Diagnostics. Both tests are *in vitro* rapid qualitative tests that detect Oxycodone in urine and use the same cutoff concentration. The scientific principle of both devices is a solid phase chromatographic immunoassay. In the performance study, Status DS OXY test showed 98% agreement for positive samples and 96% for negative samples compared to the reference test, while MedTox Oxycodone showed 96% and 97% agreement, respectively, indicating the two test devices are substantially equivalent.

Conclusion: The Status DS™ OXY test is substantially equivalent in assay principle and performance to the MedTox Oxycodone, k060351 by MedTox Diagnostics. The test is safe and effective for professional and laboratory use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

PRINCETON BIOMEDITECH CORP.
KYUNG-AH KIM
DIRECTOR, OPERATIONS/QUALITY SYSTEMS
4242 U.S. HIGHWAY 1
MONMOUTH JUNCTION NJ 08852-1905

Re: K130650
Trade/Device Name: Status DS OXY
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG
Dated: January 10, 2014
Received: January 13, 2014

Dear Dr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

k130650

Device Name

Status DS™ OXY

Indications for Use *(Describe)*

The Status DSTM OXY is an immunochromatograhic test for the qualitative detection of Oxycodone in urine samples. The detection cut-off concentration of Oxycodone is 100 ng/mL. The test may be read visually or by using a DXpress™ Reader. It is intended for clinical laboratory use only.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Avis T. Danishefsky -S